

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468144	(X3) Date Survey Completed 02/12/2026
Name of Provider or Supplier Five Rivers Medical Center	Street Address, City, State 2801 Medical Center Drive, Pocahontas, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of policy and procedure and interview it was determined that the laboratory failed to define a shift in quality control results and state what corrective action(s) to take when a shift is identified and the method to calculate standard deviations for unassayed chemistry controls. Findings follow: 1: A. Upon request, the laboratory could not produce policies and procedures that defined shifts in quality control results and corrective actions to take in the event of shifts. B. In an interview on 2/11/26 at 10:43am the technical supervisor confirmed that policies and procedures</p>

defining shifts in control results and corrective actions to follow in the event of shifts were not available. 2: A. Upon request, the laboratory could not produce policies and procedures for calculation of standard deviations for unassayed chemistry controls. B. Chemistry Control Procedures referenced standard deviations for determination of whether a control passed or failed. C. In an interview on 2/11/26 at 10:47am the technical supervisor confirmed that policies and procedures for calculating standard deviations for unassayed chemistry controls were not available.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory policy and procedure, Levey-Jennings (LJ) Reports for January 2025 through May 2025 of Prothrombin (PT) Coagulation analysis, and through interviews with laboratory staff; the laboratory failed to monitor, over time, the accuracy of coagulation test results. Survey findings include: A) A review of the "Coagulation Procedure Manual" did not define trends and shifts, or the corrective actions for shifts in control results. B) A review of the 1/1/25 through 5/31/25 ACL Elite Levey-Jennings charts for test PT showed: January level one controls above the mean on 31/31 days of testing, February level one controls above the mean on 28/28 days of testing, March level one controls above the mean for 29/31 days, and May level one controls above the mean for 29/31 days. C) A review of the quality assurance records 2025 found no mention of shifts in PT controls. D) Upon request, the laboratory was unable to provide documentation of corrective action taken to address shifts in PT analysis. E) In an interview, at 2/11/26 at 10:43am, the technical supervisor confirmed the shifts were present without documented corrective actions.

D5479

CONTROL PROCEDURES
CFR(s): 493.1256(e)(5)(g)

(e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, control lot rollover, and interview it was determined that the laboratory failed follow manufacturer's instructions for establishing the geometric mean for new coagulation controls. Findings follow: A. The manufacturer's instructions for the ACL Elite instrument "Hemostasis Performance Verification Manual " Rev B (April 2014) states "Refer to CLSI (Clinical and Laboratory Standards Institute) C28-A2 for full details" and "If the INR

(International Normalized Ratio) system is utilized to report PT (Prothrombin Time) note the geometric mean value of the PT normal reference range interval in seconds and use along with the lot specific ISI (International Sensitivity Index) value in the INR setup calculation page." B. Upon review of the reference interval worksheet, no evidence showed that the geometric mean rather than the arithmetic mean was used to calculate the mean normal prothrombin time for the local patient population. C. Upon request, the laboratory could not produce documentation that manufacturers instructions referring to CLSI C28-A2 were followed. D. In an interview on 2/11/26 at approximately 10:50am the technical supervisor confirmed that the documentation of the calculation of mean normal prothrombin time for the local patient population did not conform to the manufacturers recommendations.